

**REMARKS/ARGUMENTS**

**Claims**

By the present amendment, three (3) independent claims have been amended, zero (0) independent claims have been added, zero (0) dependent claims have been added, and zero (0) claims have been cancelled. Claims 1-33 are currently pending. No claim fees are believed payable. Applicants respectfully submit that no new matter has been added by the way of these amendments.

Claim 1 has been amended to specify that the cap is removable and that the injection prevention component disposed generally proximal to the cap distal face and distal to the distal end orifice. Support for this amendment can be found in the specification as filed in at least the following locations: Figs. 3-6 and 9-10 and page 8, line 21 through page 9, line 10; page 9, line 20 through page 10, line 12; page 10, lines 13-23; page 11, lines 13-16; and page 12, line 17 through page 13, line 4. As such, Applicants respectfully submit that no new matter has been added by way of this amendment to claim 1.

Claim 28 has been amended to specify that the cap is removable and that the a means for preventing the injection piston from moving from a locked position to a discharged position are partially located distal to the distal end orifice. Support for this amendment can be found in the specification as filed in at least the following locations: Figs. 3-6 and 9-10 and page 8, line 21 through page 9, line 10; page 9, line 20 through page 10, line 12; page 10, lines 13-23; page 11, lines 13-16; and page 12, line 17 through page 13, line 4. As such, Applicants respectfully submit that no new matter has been added by way of this amendment to claim 28.

Claim 33 has been amended to specify that the injector has a distal end orifice and that the locking mechanism is partially located distal to the distal end orifice. Support for this

amendment can be found in the specification as filed in at least the following locations: Figs 1, 3-6 and 9-10 and page 7, line 21; page 8, line 21 through page 9, line 10; page 9, line 20 through page 10, line 12; page 10, lines 13-23; page 11, lines 13-16; and page 12, line 17 through page 13, line 4. As such, Applicants respectfully submit that no new matter has been added by way of this amendment to claim 33.

### **RESPONSE TO OFFICE ACTION DATED DECEMBER 15, 2004**

In the Office Action dated December 15, 2004, claims 1 and 28 were rejected under 35 U.S.C. § 102(e) as being anticipated by United States Patent No. 6,264,629 (Landau), claims 1 and 28 were also rejected under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 6,132,395 (Landau et al.) and claims 2-27 and 29-32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Landau in view of Landau et al. Finally, claim 33 was rejected on the grounds that the steps of claim 33 are considered inherent to the apparatus of the Landau and Landau et al. patents and accordingly would have been considered obvious. Each of these rejections is respectfully traversed.

#### **I. Landau Does Not Anticipate Claims 1 or 28**

To establish a prima facie case of anticipation, the Federal Circuit has stated that it “requires the disclosure in a single prior art reference of each element of the claim under consideration.” *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); *see also* MPEP § 2131. It is not enough, however, that the prior art reference disclose all the claimed elements in isolation. Rather, “anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim.” *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984); *see also In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Furthermore, “[t]he identical invention must be shown in as complete detail as contained in the...claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Applicant respectfully submits that as currently amended neither claim 1 nor claim 28 is anticipated under § 102(e) by Landau. First, claims 1 and 28 have been amended to specify that the cap is removable. Landau does not disclose either explicitly or inherently a removable cap. In the Office Action, the plastic body 40 in Landau is stated as being a cap. The plastic body 40 is not a cap nor is it removable. As explained in Landau at 5:13-31 and shown in Figures 3-6, the drug cartridge 14 includes a cylindrical body 30 with external threads 32. Landau then states that:

[p]referably, a thread locking compound, such as an anaerobic adhesive, is applied to the threads 32 of the cartridge 14 when it is assembled to the body portion 12b during manufacture of the device 10. Alternatively, a self-locking thread design or a thread-locking feature may be used on the device 10 to prevent the drug injection cartridge 14 from being removed from the device 10. Thus, the cartridge is not removable from the device 10, and the device 10 and cartridge 14 are disposed of after the first and only injection effected with the device 10.

Landau at 5:22-31. Thus, the Landau device is intended to be a single-use device (*see* Abstract and Summary of the Invention at 2:44-45) with no removable parts as the threaded connection used for assembly cannot be unthreaded due to the use of an adhesive or self-locking threads. Because claims 1 and 28 have been amended to specify that the cap is removable and Landau does not disclose either explicitly or inherently every limitation of claim 1 or 28, Landau cannot anticipate claims 1 or 28, nor can it anticipate any claim dependent from either claim 1 or 28.

Second, claim 1 has been amended to specify that the injection prevention component is disposed generally proximal to the cap distal face and distal to the distal end orifice and claim 28 has been amended to specify that the means for preventing the injection piston from moving from a locked position to a discharged position are partially located distal to the distal end orifice. At a minimum, Landau does not disclose either of these two amended claim features.

The Office Action contends that the plug member 44 of Landau discloses the injection prevention component of claim 1 and the means of claim 28. Landau discloses neither.

Figure 3 of Landau shows the plug member 44 located within the outlet orifice 36b. However, the plug member 44 is located *proximal* to the injection nozzle opening 18. Claim 1 has been amended to specify that the injection prevention component is disposed generally proximal to the cap distal face and *distal* to the distal end orifice. Claim 28 has been amended to specify that the means for preventing the injection piston from moving from a locked position to a discharged position are partially located *distal* to the distal end orifice. Moreover, the plug member 44 in Landau is present to sealingly close the outlet orifice 36b when the injector is in the storage configuration. (Landau at 5:63-65) and does not serve to disable an injector and prevent accidental injection. As such, Landau does not disclose either explicitly or inherently every limitation of claims 1 or 28 as amended; therefore, Landau cannot anticipate claims 1 or 28, nor can it anticipate any claim dependent from claims 1 and 28. Applicants respectfully request that the § 102(e) rejection based upon Landau be withdrawn.

## **II. Landau et al. Does Not Anticipate Claims 1 or 28**

Claims 1 and 28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Landau et al. As previously set forth, anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration as well as requiring that the disclosure of each and every element of the claimed invention also be arranged as in the claim.

Applicant respectfully submits that as currently amended neither claim 1 nor claim 28 is anticipated under § 102(b) by Landau et al. First, claims 1 and 28 have been amended to specify that the cap is removable. Landau et al. does not disclose either explicitly or inherently a removable cap. The Office Action has not specified which components illustrated in Figures 1,

12A, 17A and 17B of Landau et al. disclose a cap. Furthermore, none of the figures identified in the Office Action disclose a removable cap. The nozzle 514 in Figures 17A and 17B of Landau is merely a component having a plurality of tangs (Landau at 4:1-9) to hold the cartridge 12 in place for injection. This cartridge/nozzle assembly allows for prefilled cartridges to be partially assembled with the nozzle prior to insertion into a needleless injector. (Landau at 4:34-42). Because claims 1 and 28 have been amended to specify that the cap is removable and Landau et al. does not disclose either explicitly or inherently every limitation of claim 1 or 28, Landau cannot anticipate claims 1 or 28, nor can it anticipate any claim dependent from either claim 1 or 28.

Second, claim 1 has been amended to specify that the injection prevention component is disposed generally proximal to the cap distal face and distal to the distal end orifice. Claim 28 has been amended to specify that the means for preventing the injection piston from moving from a locked position to a discharged position are partially located distal to the distal end orifice. At a minimum, Landau et al. does not disclose either of these two amended claim features. The Office Action contends that Landau et al. discloses the injection prevention component of claim 1 and the means of claim 28. Landau et al. discloses neither.

Landau et al. illustrates (Figs 17A and 17B) and describes (7:59 to 8:13) the use of an aluminum seal 568 and an elastomeric membrane 566 to seal the prefilled cartridge 512. The aluminum seal 568 and elastomeric membrane 566 is designed to burst open when loaded into a needleless injector and prepared for use. (Landau et al. at 6:51-60). Neither the aluminum seal 568 nor the elastomeric membrane 566 of Landau et al. prevent injection as they are designed to fail in order to facilitate injection and are present in order to seal the cartridge 14. More importantly, the aluminum seal 568 and elastomeric membrane 566 are located *proximal* to the

orifice 558. Claim 1 has been amended to specify that the injection prevention component is disposed generally proximal to the cap distal face and *distal* to the distal end orifice. Claim 28 has been amended to specify that the means for preventing the injection piston from moving from a locked position to a discharged position are partially located *distal* to the distal end orifice. As such, Landau et al. does not disclose either explicitly or inherently every limitation of claims 1 or 28 as amended; therefore, Landau et al. cannot anticipate claims 1 or 28, nor can it anticipate any claim dependent from claims 1 and 28. Applicants respectfully request that the § 102(b) rejection based upon Landau et al. be withdrawn.

### **III. Landau In View Of Landau et al. Cannot Render Claims 2-27 and 29-32 Obvious**

Claims 2-27 and 29-32 currently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Landau in view of Landau et al. Even assuming, *arguendo*, that motivation to combine Landau with Landau et al. did exist at the time of Applicants' invention, which is not admitted herein, no *prima facie* case of obviousness can be made out because Landau in view of Landau et al. does not disclose each of the claim limitations of the present claims.

It is well settled that in order to establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (C.C.P.A. 1974). For the reasons described above, neither Landau nor Landau et al. teach every limitation of claims 1 and 28 as amended. Indeed, the claim limitations missing from Landau are likewise missing from Landau et al. such that the combination does not teach every limitation of claims 1 and 28 as amended. Therefore, the combination of Landau in view of Landau et al. does not teach or suggest all the claim limitations and thereby lacks a necessary element for establishing a *prima facie* case of obviousness. MPEP § 2143. Applicants

respectfully request that the § 103(a) rejection based upon Landau in view of Landau et al. be withdrawn.

**IV. The Method Steps of Claim 33 Are Not Inherent to Either Landau or Landau et al.**

Claim 33 stands rejected under 35 U.S.C. § 103(a) as inherent to the apparatuses of Landau and Landau et al. In order for a reference to inherently disclose a claim limitation, that limitation must necessarily be present in the reference and be so recognized by a person of ordinary skill in the art. *Electro Medical Systems S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 32 USPQ2d 1017 (Fed. Cir. 1994). “Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (C.C.P.A. 1981).

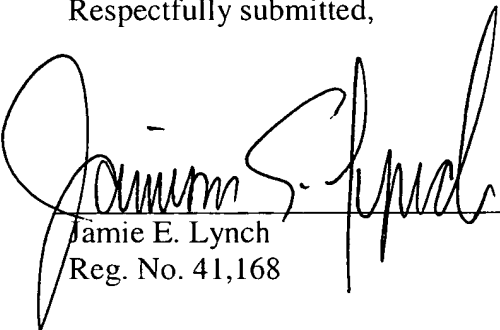
Claim 33 has been amended to specify that the injector has a distal end orifice and that the locking mechanism is partially located distal to the distal end orifice. Additionally, claim 33 as filed contains the steps of “loading a cap” and “removing a cap.” Thus, as set forth by these method steps, the cap is removable. For the reasons described above, neither Landau nor Landau et al. teach a removable cap nor do the references (alone or in combination) teach a locking mechanism is partially located distal to the distal end orifice. Due to the deficiencies of Landau in view of Landau et al. the method of claim 33 cannot necessarily result from the apparatuses described in Landau and Landau et al. Applicants respectfully request that the § 103(a) rejection based upon Landau in view of Landau et al. for claim 33 be withdrawn.

**V. Concluding Remarks**

It is to be understood though that no admission is made nor implied by the present amendment as to the fact that the prior art cited may be relevant. Indeed, this amendment is made *solely* to expedite the prosecution of the present application.

Applicants submit that in light of the amendments and arguments provided herein, all pending claims of the present Application are in condition for allowance. Applicants respectfully request entry of the proposed amendment and allowance of the claims. If, in the opinion of the Examiner, a telephone conference would help expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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